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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,739	11/08/2001	James C. Copeland	OXR 2 0025	4971

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,739	COPELAND ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-13,16-26 and 28-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-13,16-26 and 28-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5,7-13, 16-26 and 28-35 are under consideration.

Claims 6, 14, 15 and 27 have been canceled.

Rejections/Objections Withdrawn

1. Claims 10-12,15-17,20, 22 rejected under 35 U.S.C. 102(b) as being anticipated by Blondin et al (US Pat. 4,808,517), in light of the amendments of independent claims 10 and 20 to recite E.coli cytoplasmic membranes which are not disclosed in Blondin et al.

Rejections Maintained

1. Claims 1-5,7-13, 16-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992, English Translation) in view of Adler (US Pat. 4,476,224) for reasons of record in paper number 6, # 11 and responses to remarks set forth below.

2. Claims 28-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) for reasons of record in paper number 6,#12, and responses to remarks set forth below.

3. Claims 1-5,7-13, 16-26 and 28-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad (1992, English translation) in view of Copeland et al (US Pat. 5,830,746) , is maintained for reasons of record and responses set forth below.

4. Claims 1-5,7-13, 16-26 and 28-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad (1992, English translation) in view of Fung et al (US Pat. 5,405,773), , is maintained for reasons of record and responses set forth below.

Response to Arguments

5. Applicant's arguments filed August 5, 2005 have been fully considered but they are not persuasive.

6. Applicant asserts that the instantly claimed invention is not disclosed and/or remotely discussed in any of the references cited, there is no motivation to combine the references, "all of the independent claims recite that the oxygen scavenging membrane fragment is derived from the respiratory system of an organism normally sensitive to azide" and the oxygen scavenging enzymes or membrane fragments that comprise the oxygen scavenging enzymes if combined with azide would be expected to not form an anaerobic environment because the "azide would kill the membrane fragments" .

1. In response to Applicant's assertion that compositions of azide and the oxygen scavenging enzymes or membrane fragments that comprise the oxygen scavenging enzymes is contrary to accepted wisdom in the art because the "azide would kill the membrane fragments", it is the position of the examiner that:

- various Patents (previously made of record) were cited to show compositions of a glucose or alcohol oxidase together with azide (5081015; 4414334; 4894339; 4810633; 4485016; 4254220; 3721607; 4430427) and that alcohol oxidase and glucose oxidase are the enzymes present in the membrane fragments (see US PG-Pub paragraph [0029] and US Pat. 4,476,224 Adler et al, which define the membrane fragments to comprise glucose oxidase and alcohol oxidase enzymes), and the enzymes were found to still be functional enzymes in presence of the azide.
- US Patent 4414334 teaches that with 0.02 weight percent sodium azide in an enzyme composition of alcohol oxidase and catalase, the high level of enzyme activity could

be maintained within a designated range of pH and temperature (see Detailed Description, paragraphs 18 and 21).

- Tabakhovskii et al (1989, English abstract page 540) teaches that E.coli membranes evidenced ultrastructural changes during plasmolysis, and the dynamic rearrangement of the membrane proceeded and was not inhibited by the presence of azide (see last sentence). The membranes were still functional in the presence of azide or methiolate.
- Additionally, anaerobic bacteria ATPase activity has been shown to be only partially inhibited by 15 microMolar azide and thus viability maintained (Milgrom et al, 1988).
- Merad et al added 0.1% azide to anaerobic bacteria culture media and found the membranes of the anaerobes to be no killed but provided growth conditions that selected permitted the growth of strict anaerobes over that of facultative anaerobes (see reference page 167 and English translation page 7, section IV first paragraph).
- Hope et al (1991, abstract only) teach that an anaerobe in the presence of cyanide and a sugar produce ammonia under anaerobic conditions and thus are still viable and growing under these conditions; the membranes of the microorganism are not killed.
- Tillonen et al teach that azide also inhibits the enzyme catalase which is present in aerobic and facultative anaerobic bacteria but is not present in strict anaerobes, and would therefore function to selectively inhibit catalase containing bacteria in their growth process.
- Sjogren et al teach that azide is only moderately inhibitory of E.coli, about 15% (abstact).

Based upon the evidence provided in the prior art that azide can be added to a composition of oxygen scavenging membrane enzymes and still permit enzymatic activity, as well as azide not

effecting strict anaerobic bacterial catalase enzymatic activity because they do not generally produce catalase, but would effectively inhibit catalase of aerobes and facultative anaerobes, the addition of azide to culture medium is not completely contrary to accepted wisdom in the art.

Clearly Merad selects against facultative microbes with azide to promote the growth of anaerobic bacteria and Adler who produces an anaerobic growth environment by removing oxygen to promote the growth of anaerobic bacteria are combinable. In light of the fact that E.coli membrane oxygen scavenging enzymes are able to still enzymatically function in the presence of azide and are not killed by its presence, Merad in view of Adler obviate the instantly claimed invention as now claimed.

2. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the prior art teaches compositions of alcohol oxidase and/or glucose oxidase with azide which still permitted enzymatic activity, and the applied reference the combination being Merad in view of Adler is not improper hindsight reasoning in light of the fact that both references sought to isolate anaerobic bacteria from a mixed culture that included both anaerobes and facultative anaerobes, and Merad found that through the addition of azide to the culture medium anaerobic bacteria would preferentially grow and Adler et al teach the utilization of bacterial or eukaryotic membranes that contain glucose oxidase or alcohol oxidase enzymes that

assisted in the creation of an anaerobic growth environment to preferentially grow anaerobic bacteria, therefore the combination of Merad in view of Adler is not contrary to teaching in the prior art.

3. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

There is a reasonable expectation of success because both reference teach successful methods of isolating anaerobic bacteria with growth media that provides a growth advantage to anaerobic strains and species over facultative anaerobes, and the general state of the art was that glucose oxidase or alcohol oxidase could evidence enzymatic activity in the presence of azide or cyanide (catalase inhibitor and strict anaerobes lack catalase, see Tillonen et al (1998)).

In the absence of unexpected results, Merad in view of Adler still obviates the instantly claimed invention. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining flows logically from their having been individually taught in the prior art" In re Kerkhoven (205 USPQ 1069, CCPA 1980.

4. Applicant asserts that growth media of Merad and Adler et al lacked a hydrogen donating substance.

5. It is the position of the examiner that while the exact words "hydrogen donating substance" is not used, the definition of this phrase in Applicant Specification includes " (i.e., an organic substrate) may be necessary in order for the membrane fragments to perform their oxygen removing functions. Suitable hydrogen donors are lactic acid, succinic acid, alpha-glycerol phosphate, formic acid, malic acid, and where available, their corresponding salts."

Based upon Applicant's definition of "hydrogen donating substance" to include organic substrates, and the media of Merad et al being Trypiticase broth or Columbia agar in light of evidence provided by King (US Pat. 5,498,528, col. 5-6), the media bases of Merad et al contained glucose or corn starch which are organic substrates.

Additionally Adler specifically teaches the addition of a hydrogen donor (see abstract, claims) and exemplifies the addition of sodium lactate (see Example 3, Adler, col. 4, line 65.) The assertion that the growth media of Merad et al and Adler lacked a hydrogen donating substrate mischaracterizes both references.

7. **(35 U.S.C. 103(a) Rejection Maintained)** The rejection of claims 1-35 under 35 U.S.C. 103(a) as being unpatentable over Merad (1992, English translation) in view of Copeland et al (US Pat. 5,830,746) is traversed on the same grounds set forth above for Merad in view of Adler.

8. The examiner's responses are incorporated herein by reference as set forth above for Merad in view of Adler. It is prima facie obvious to combine two compositions each of which is

taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining flows logically from their having been individually taught in the prior art" In re Kerkhoven (205 USPQ 1069, CCPA 1980.

9. (35 U.S.C. 103(a) Rejection Maintained) The rejection of claims 1-5,7-13, 16-26 and 28-35 under 35 U.S.C. 103(a) as being unpatentable over Merad (1992, English translation) in view of Fung et al (US Pat. 5,405,773) is traversed on the same grounds set forth above for Merad in view of Adler.

10. The examiner's responses are incorporated herein by reference as set forth above for Merad in view of Adler. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining flows logically from their having been individually taught in the prior art" In re Kerkhoven (205 USPQ 1069, CCPA 1980.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 25, 2005

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